General

Guideline Title

Medical management of first-trimester abortion.

Bibliographic Source(s)

American College of Obstetricians and Gynecologists (ACOG). Medical management of first-trimester abortion. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2014 Mar. 17 p. (ACOG practice bulletin; no. 143). [113 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: American College of Obstetricians and Gynecologists (ACOG). Medical management of abortion. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2005 Oct. 12 p. (ACOG practice bulletin; no. 67). [79 references]

Recommendations

Major Recommendations

The grades of evidence (I–III) and levels of recommendations (A–C) are defined at the end of "Major Recommendations" field.

The following recommendations are based primarily on good and consistent scientific evidence (Level A):

- Based on efficacy and adverse effect profile, evidence-based protocols for medical abortion are superior to the U.S. Food and Drug Administration (FDA)-approved regimen. Vaginal, buccal, and sublingual routes of misoprostol administration increase efficacy, decrease continuing pregnancy rates, and increase the gestational age range for use as compared with the FDA-approved regimen.
- Regimens that use low doses of mifepristone (200 mg) have similar efficacy and lower costs compared with to those that use mifepristone at 600 mg.
- Women can safely and effectively self-administer misoprostol at home as part of a medical abortion regimen.
- Medical abortion also can be provided safely and effectively by nonphysician clinicians.
- Follow-up after receiving mifepristone and misoprostol for medical abortion is important, although an in-clinic evaluation is not always necessary.
- Misoprostol-only medical abortion regimens are significantly less effective than those that use a combination of mifepristone and misoprostol.

The following recommendations are based primarily on limited scientific evidence (Level B):

- Because teratogenicity of medical abortifacients becomes an important issue if the pregnancy continues, patients must be counseled before

medical abortion treatment of the need for a surgical abortion in the event of a continuing pregnancy.
- Before medical abortion is performed, gestational age should be confirmed by clinical evaluation or ultrasound examination.
- Nonsteroidal antiinflammatory drugs, such as ibuprofen, are not contraindicated in women who undergo a medical abortion and are appropriate first-line agents for pain management.
- Buccal administration of misoprostol may result in a lower risk of serious infection compared with vaginal administration.
- Medical abortion can be provided safely and effectively via telemedicine with a high level of patient satisfaction; moreover, the model appears to improve access to early abortion in areas that lack a physician health care provider.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- Women who undergo medical abortion may need to access emergency surgical intervention, and it is medically appropriate to provide referral to another health care provider. However, state or local laws may have additional requirements.
- Clinicians who wish to provide medical abortion services either should be trained in surgical abortion or should be able to refer to a clinician trained in surgical abortion.
- No strong data exist to support the universal use of prophylactic antibiotics for medical abortion.
- Rhesus (Rh) testing is standard of care in the United States, and RhD immunoglobulin should be administered if indicated.

Definitions:

Grades of Evidence

I: Evidence obtained from at least one properly designed randomized controlled trial.

II-1: Evidence obtained from well-designed controlled trials without randomization.

II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Levels of Recommendation

Level A—Recommendations are based on good and consistent scientific evidence.

Level B—Recommendations are based on limited or inconsistent scientific evidence.

Level C—Recommendations are based primarily on consensus and expert opinion.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Unwanted pregnancy

Guideline Category

Management

Clinical Specialty

Emergency Medicine

Obstetrics and Gynecology

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To present evidence of the effectiveness, benefits, and risks of first-trimester medical abortion and provide a framework for counseling women who are considering medical abortion

Target Population

Pregnant women who:

- Have considered their options and have made the decision to have an abortion
- Meet the gestational age criteria for medical abortion (up to 63 days of gestation as calculated from the first day of the last menstrual period)

Interventions and Practices Considered

1. Clinical evaluation or ultrasonography before abortion to confirm gestational age
2. Medical abortion using one of the following regimens:
    - Misoprostol alone (vaginal, buccal, or sublingual)
    - Mifepristone plus misoprostol
3. Counseling patients about of the need for a surgical abortion in the event of a continuing pregnancy
4. Rhesus (Rh) testing
5. RhD immunoglobulin as indicated
6. Prophylactic antibiotics (not recommended for universal use)
7. Nonsteroidal antiinflammatory drugs for pain management
8. Emergency surgical intervention or referral if needed
9. Follow-up

Major Outcomes Considered

- Complete abortion rates
- Need for surgical evacuation
- Overall success rate
- Incidence of adverse effects associated with medical abortions
- Days to weeks to complete

Methodology

Methods Used to Collect/Select the Evid

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 2000 to November 2013. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles. When reliable research was not available, expert opinions from obstetrician-gynecologists were used.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force (1989):

I: Evidence obtained from at least one properly designed randomized controlled trial.

II-1: Evidence obtained from well-designed controlled trials without randomization.

II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician-gynecologists were used. See also the "Rating Scheme for the Strength of the Recommendations" field regarding Level C recommendations.

Rating Scheme for the Strength of the Recommendations

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A—Recommendations are based on good and consistent scientific evidence.

Level B—Recommendations are based on limited or inconsistent scientific evidence.

Level C—Recommendations are based primarily on consensus and expert opinion.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate medical management of first-trimester abortion

Potential Harms

- Bleeding and cramping will be experienced by most women undergoing medical abortion and are necessary for the process to occur.
- Adverse effects commonly associated with mifepristone use include nausea, vomiting, diarrhea, headache, dizziness, and thermoregulatory effects (see Table 1 in the original guideline document). The incidence of each adverse effect is based on the regimen used (especially the

prostaglandin analogue), the dose and route of administration of the prostaglandin analogue, and the gestational age. Gastrointestinal adverse effects are less common when misoprostol is administered vaginally as compared with regimens that use oral, buccal, or sublingual misoprostol. Buccal and sublingual administration cause similar adverse effects, with the sublingual route associated with a higher rate of chills.

- Overall, large series demonstrate that less than 1% of women will need emergency curettage because of excessive bleeding. Moreover, the risk of clinically significant bleeding and transfusion may be lower in women who undergo medical abortion of gestations up to 49 days compared with those who undergo medical abortion of gestations of more than 49 days; this risk will vary based on the regimen used.
- Because teratogenicity of medical abortifacients becomes an important issue if the pregnancy continues, patients must be counseled before medical abortion treatment of the need for a surgical abortion in the event of a continuing pregnancy.
- The overall risk of serious infection with medical abortion is very low and buccal administration of misoprostol may result in a lower risk of serious infection compared with vaginal administration.
- Women are not good candidates for medical abortion if they are unable or unwilling to adhere to care instructions, desire quick completion of the abortion process, are not available for follow-up contact or evaluation or cannot understand the instructions because of language or comprehension barriers.

Contraindications

Contraindications

- Most studies of medical abortion with mifepristone and misoprostol exclude women with anemia who have hemoglobin levels of less than 9.5 g/dL or less than 10 g/dL; accordingly, the safety of medical abortion in women with anemia is unknown. Other medical contraindications to abortion with mifepristone regimens include confirmed or suspected ectopic pregnancy, intrauterine device (IUD) in place, current long-term systemic corticosteroid therapy, chronic adrenal failure, known coagulopathy or anticoagulant therapy, and intolerance or allergy to mifepristone.
- Misoprostol should not be used in women who have an allergy or intolerance to misoprostol or other prostaglandins.

Qualifying Statements

Qualifying Statements

The information is designed to aid practitioners in making decisions about appropriate obstetric and gynecologic care. These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Audit Criteria/Indicators

Foreign Language Translations

Patient Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Timeliness

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2001 Apr (revised 2014 Mar)

Guideline Developer(s)

American College of Obstetricians and Gynecologists - Medical Specialty Society

Society of Family Planning - Professional Association

Source(s) of Funding

American College of Obstetricians and Gynecologists (ACOG)

Guideline Committee

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins—Gynecology

Composition of Group That Authored the Guideline

This Practice Bulletin was developed by the Committee on Practice Bulletins—Gynecology and the Society of Family Planning with the assistance of Mitchell D. Creinin, MD and Daniel A. Grossman, MD.

American College of Obstetricians and Gynecologists (ACOG) committees are created or abolished and their overall function defined by the Executive Board. Appointments are made for one year, with the understanding that such appointment may be continued for a total of three years. The majority of committee members are Fellows, but Junior Fellows also are eligible for appointment. Some committees may have representatives from other organizations when this is particularly appropriate to committee activities. The president elect appoints committee members annually.

Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

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This guideline updates a previous version: American College of Obstetricians and Gynecologists (ACOG). Medical management of abortion. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2005 Oct. 12 p. (ACOG practice bulletin; no. 67). [79 references]

Guideline Availability

Electronic copies: None available

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 933104, Atlanta, GA 31193-3104; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site.

Availability of Companion Documents

A proposed performance measure is included in the original guideline document.

Patient Resources

The following is available:

- Frequently asked questions: induced abortion. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2011 Oct. 3 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Obstetricians and Gynecologists (ACOG) Web site. Copies are also available in Spanish.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI on September 22, 2004. The information was verified by the guideline developer on December 9, 2004. This summary was updated by ECRI on July 21, 2005 following the Food and Drug Administration (FDA) advisory on Mifeprex

(mifepristone). This summary was updated by ECRI on March 7, 2006 following the updated FDA advisory on Mifeprex (mifepristone). This summary was updated most recently on April 20, 2006. The information was reaffirmed by the guideline developer in 2009 and updated by ECRI Institute on December 17, 2010. This summary was updated by ECRI Institute on May 2, 2014. This summary was updated by ECRI Institute on September 18, 2015 following the U.S. Food and Drug Administration advisory on non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs).

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